K122578

FEB 25 2013

510(k) Summary

This 510(k) summary is submitted in accordance with the requirements of 21 C.F.R. Part 807.92.

Purpose of Submission: Vital Images, Inc. hereby submits this traditional 510(k) to provide notification submission of our new Vitrea CT Transcatheter Aortic Valve Replacement (TAVR) Planning application within our already cleared Vitrea platform.

Submitter: Vital Images, Inc.
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Establishment Registration: 2134213

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510(k) Type: Traditional

Summary Date: August 21, 2012

Device Name

Trade Name: Vitrea CT Transcatheter Aortic Valve Replacement Planning
Common Name: Picture Archiving and Communications System
Classification Name: System, Image Processing, Radiological (21 C.F.R. 892.2050, LLZ)

Predicate Device: Pie Medical Imaging B.V., 3mensio Workstation (K120367)

Device Description:
Vitrea CT Transcatheter Aortic Valve Replacement (TAVR) Planning is a non-invasive post-processing application designed to assist medical professionals with the assessment of the aortic root and in pre-operational planning and post-operative evaluation of transcatheter aortic valve replacement procedures.

It allows cardiologists, radiologists and clinical specialists to select patient CT studies from various data sources, view them, and process the images with the help of a comprehensive set of tools. It provides assessment and measurement of different structures of the heart and vessels relevant to approach planning. It provides simple techniques to assess the feasibility of a trans-apical, iliac, or subclavian approach to heart structures for replacement or repair procedures.

Intended Use / Indications for Use:
Vitrea CT Transcatheter Aortic Valve Replacement (TAVR) Planning is a non-invasive post-processing application designed to assist medical professionals with the assessment of the aortic valve and in pre-operational planning and post-operative evaluation of transcatheter aortic valve replacement procedures.

Vitrea CT Transcatheter Aortic Valve Replacement (TAVR) Planning includes general functionality such as:

- The software processes CT (computed tomography) image data to provide 3D segmentation of heart structures and vessels relevant to approach planning.
- The user can review the 2D and 3D images to select and plan the delivery path.
- The user can determine C-arm angles for use during the procedure.
- The user can verify and adjust the results of segmentation and cross-section measurements.
- The software provides visualization techniques such as volume rendering, MIP, MPR and curved MPR.
- The user can identify and edit contours and the centerline automatically or manually.
- The user can generate a report with relevant approach planning data and measurements for device sizing.
- The software can provide visualization of calcium.
- The user can generate tortuosity calculations along a centerline.

Technological Characteristics Comparison with the Predicate Device:
Vitrea CT Transcatheter Aortic Valve Replacement (TAVR) Planning is a noninvasive post-processing application for the Vitrea platform to assist medical professionals with the assessment of the aortic root and in pre-operational planning and post-operative evaluation of transcatheter aortic valve replacement procedures.

Vitrea CT Transcatheter Aortic Valve Replacement (TAVR) Planning leverages the basic functionality and technology of the existing 510(k) cleared Vitrea platform (K071331). It is an advanced application that extends the functionality of the platform for specific uses. The intended use of Vitrea CT Transcatheter Aortic Valve Replacement (TAVR) Planning (to assist medical professionals with the assessment of the aortic valve and in pre-operational planning and post-operative evaluation of transcatheter aortic valve replacement procedures) is substantially equivalent to the cleared intended use of Pie Medical Imaging B.V. 3mensio Workstation [K120367] (assessment of structures of the heart and vessels for pre-operational planning and sizing for cardiovascular interventions and surgery).

The below technological comparison table shows the equivalence between Vitrea CT Transcatheter Aortic Valve Replacement (TAVR) Planning and the predicate device.

Vitrea CT Transcatheter Aortic Valve Replacement (TAVR) Planning (Submission Subject)	Pie Medical Imaging B.V., 3mensio Workstation (K120367) (Predicate Device)	Noted Differences
Target Population:		
It is intended for a patient who is a candidate for an Aortic Valve (AV) replacement through TAVR procedures. The software enables assessment and measurement of aortic valve and related ventricles. It provides simple techniques to assess the feasibility of a trans-apical, iliac (transfemoral), or subclavian approach to structures for replacement or repair procedures.	Same 3mensio Structural Heart enables assessment and measurement of different structures of the heart, e.g. aortic valve, mitral valve, and ventricles. It provides simple techniques to assess the feasibility of a trans-apical, transfemoral (iliac), or subclavian approach to structures for replacement or repair procedures.	None

Vitrea CT Transcatheter Aortic Valve Replacement (TAVR) Planning (Submission Subject)	Pie Medical Imaging B.V., 3mensio Workstation (K120367) (Predicate Device)	Noted Differences
Intended Users:		
The software allows cardiologists, radiologists and clinical specialists to select patient CT studies from various data sources, view them, and process the images with the help of a comprehensive set of tools. It provides assessment and measurement of different structures of the heart and vessels relevant to approach planning.	Same 3mensio Workstation is a software solution that is intended to provide cardiologists, radiologists and clinical specialists additional information to aid them in reading and interpreting DICOM-compliant medical images of structures of the heart and vessels.	None
Anatomical Sites:		
The software enables assessment and measurement of aortic valve and related ventricles. It provides simple techniques to assess the feasibility of a trans-apical, iliac (transfemoral), or subclavian approach to structures for replacement or repair procedures.	Same 3mensio Structural Heart enables assessment and measurement of different structures of the Heart, e.g. aortic valve, mitral valve, and ventricles. It provides simple techniques to assess the feasibility of a trans-apical, transfemoral or subclavian approach to structures for replacement or repair procedures.	None
Where Used (Hospital, Home, Ambulance, etc.)		
Hospital	Hospital	None
Human Factors		
The software is designed for use on a radiology workstation.	The software is designed for use on a radiology workstation.	None
Use of Contrast		
The software requires contrast enhanced CTA images.	The software requires contrast enhanced CTA images.	None
DICOM Standard Compliance:		
The software processes DICOM-compliant CT image data.	Same 3mensio Workstation software processes DICOM-compliant CT image data.	None

Vitrea CT Transcatheter Aortic Valve Replacement (TAVR) Planning (Submission Subject)	Pie Medical Imaging B.V., 3mensio Workstation (K120367) (Predicate Device)	Noted Differences
Image Processing:		
Segmentation: The software provides segmentation, which can be manually adjusted, of the ascending aorta for aortic root measurement.	Same 3mensio Structural Heart's Aortic Root analysis tool provides segmentation, which can be manually adjusted, of the ascending aorta for aortic root measurements.	None
Centerline: The software's vessel analysis tool provides a centerline, which can be manually adjusted, of the vessels relevant to treatment planning.	Same 3mensio Workstation provides a centerline detection of vessels, which can be manually adjusted.	None
Image Display:		
The software provides an option to display vascular anatomy in stretched MPR, orthogonal, multi-dimensional, curved MPR, oblique, MIP, and MinIP views.	Same 3mensio Workstation provides many visualization and image reconstruction techniques which also include stretched MPR, orthogonal, multi-dimensional, curved MPR, oblique, MIP, and MinIP views.	None
The software provides a 3D view.	Same 3mensio Workstation provides a 3D view.	None
Image Assessment:		
C-arm Angles: The software provides C-arm angles, which can be utilized to determine the best approach to access the anatomy during the surgery.	Same 3mensio Workstation provides C-arm angulation calculations, which can be utilized to determine the best approach to access the anatomy during the surgery.	None
Tools: The software provides tools to measure angle, minimum diameter, length, and area parameters for device sizing and approach planning.	Same 3mensio Workstation provides tools to measure angle, diameter, length, and area parameters for device sizing and approach planning.	None
Calcification: The software can visualize calcium in the aortic root during iliac (transfemoral) access approach, by using existing Vitrea platform functionality.	Same 3mensio Workstation provides stretched view option to visualize calcification during transfemoral approach.	None

Vitrea CT Transcatheter Aortic Valve Replacement (TAVR) Planning (Submission Subject)	Pie Medical Imaging B.V., 3mensio Workstation (K120367) (Predicate Device)	Noted Differences
Stenosis: The software enables user to visualize and assess of stenosis by using existing Vitrea platform's *Vessel Probe* functionality (K071331).	Same 3mensio Workstation enables user to visualize and assess of stenosis.	None
Aneurysms: The software enables user to visualize and assess of aneurysms by using existing Vitrea platform's *Vessel Probe* functionality (K071331).	Same 3mensio Workstation enables user to visualize and assess of aneurysms.	None
Annulus Plane: The software provides tools for determining and manually adjusting the annulus valve plane.	Same 3mensio Workstation Structural Heart module's Aortic Root feature provides Aortic Root Analysis tool to determine and manually adjust the annulus plane.	None
Approach Planning: The software provides procedure to complete following approach planning: • Iliac (transfemoral) access • Subclavian access • Trans-apical planning	Same 3mensio Workstation structure heart module's aortic root feature provides following approach planning: • Transfemoral approach, which talks about iliac access • Subclavian approach • Apex approach, which talks about Trans-apical approach planning	None
Distribute Findings:		
The software provides tools to generate reports to distribute findings.	Same 3mensio Workstation provides reporting tools to distribute findings.	None

Summary of Non-Clinical Tests:
Vitrea CT Transcatheter Aortic Valve Replacement (TAVR) Planning was designed, developed, and tested according to written procedures that included applying risk management. Testing included verification, validation, and evaluation of previously acquired medical images.

The following quality assurance measures were applied to the development of Vitrea CT Transcatheter Aortic Valve Replacement (TAVR) Planning:

- Risk analysis
- Requirements reviews
- Design reviews
- Performance testing (Verification)
- Safety testing (Verification)
- Simulated use testing (Validation)

Verification:
The software verification team had a primary goal of assuring that software fully satisfies all expected system requirements and features. Test cases were executed against the system features and requirements. As part of creating the test cases, the verification team reviewed and monitored the Requirements Traceability Matrix ("RTM") to ensure coverage of the items within the RTM.

Validation:
The software validation team had a primary goal of assuring that software conforms to user needs and intended uses. The result of the validation team's efforts was evidence, produced by workflow testing, that system requirements and features were implemented, reviewed and met.

Internal Validation:
The software validation team provided internal validation of Vitrea CT Transcatheter Aortic Valve Replacement (TAVR) Planning. Internal validation included internal beta testing and internal user acceptance testing.

External Validation:
During external validation of Vitrea CT Transcatheter Aortic Valve Replacement (TAVR) Planning, external cardiologists and radiologists evaluated 70 TAVR cases. Each user felt that the automated segmentation within the application enabled an accurate 3D representation of the relevant anatomy. The users also felt the automated oblique provided an accurate starting point for determining the annulus valve plane. All of the users were able to review the 2D and 3D images, verify and correct the results of segmentations and initialization, create measurements, and generate reports.

The software was designed, developed and tested according to written procedures. Software testing was completed to ensure the new feature operates according to its requirements and without impact to existing functionality.

Summary of Clinical Tests:
The subject of this traditional 510(k) notification, Vitrea CT Transcatheter Aortic Valve Replacement (TAVR) Planning, did not require clinical studies to support safety and effectiveness of the software.

Cyber and Information Security:

- ***Confidentiality***
  Vitrea platform relies on built in Windows Login security to limit access to the system. The Vitrea platform can only be installed and configured by an administrator of the Windows machine.
- ***Integrity***
  Vitrea platform complies with the DICOM standard for transfer and storage of this data and does not modify the contents of DICOM instances. Vitrea platform identifies the data it produces, marking and encoding the appropriate DICOM fields.
- ***Availability***
  Vitrea platform is always available to the logged on user as long as the Windows machine itself is properly maintained.
- ***Accountability***
  Vitrea platform includes an audit capability that enables accountability by tracking authenticated and authorized user operations along with information accessed. Vitrea audit logs are time stamped, enabling correlation with Windows system logging to track information accessed by a user.

Measurement Accuracy:
Measurements and orientations in Vitrea CT Transcatheter Aortic Valve Replacement (TAVR) Planning were verified using various imaging phantoms. These imaging phantoms contain markers at known positions, distances, and angles from one another. The known positions, distances, and angles were used as input into expected results for verification tests that verified the spatial accuracy of image rendering of 2D and 3D images, the accuracy of distance, angular measurement, and navigational tools, as well as the accuracy of orientation markers within Vitrea CT Transcatheter Aortic Valve Replacement (TAVR) Planning.

Performance Standard:
No applicable mandatory performance standards or special controls exist for this device.

Substantial Equivalence:
The intended use and technological characteristics of Vitrea CT Transcatheter Aortic Valve Replacement (TAVR) Planning are substantially equivalent to the intended use and technological characteristics of the predicate device.

Conclusion:
The testing reported in this 510(k) establishes that Vitrea CT Transcatheter Aortic Valve Replacement (TAVR) Planning is substantial equivalent to the predicate device and is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 25, 2013

Vital Images, Inc.
% Mr. Ian Nemerov
Vice President, General Counsel & Secretary
5850 Opus Parkway, Suite #300
MINNETONKA MN 55343

Re: K122578
Trade/Device Name: Vitrea CT Transcatheter Aortic Valvue Replacement (TAVR) Planning
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: January 21, 2013
Received: January 22, 2013

Dear Mr. Nemerov:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122578

Device Name: Vitrea CT Transcatheter Aortic Valve Replacement (TAVR) Planning

Indications for Use:

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

(Division Sign Off)
Division of Radiological Health
Office of In Vitro Diagnostics and Radiological Health

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